# STOOL SOFTENER- docusate sodium capsule, liquid filled AmerisourceBergen (Good Neighbor Pharmacy) 46122

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# **Drug Facts**

# Active ingredient (in each softgel)

Docusate sodium 100 mg

# Purpose

Stool softener laxative

#### Uses

- relieves occasional constipation (irregularity)
- generally produces bowel movement in 12 to 72 hours

# Warnings

#### Do not use

if you are presently taking mineral oil, unless told to do so by a doctor.

#### Ask a doctor before use if you have

- stomach pain
- nausea
- vomiting
- noticed a sudden change in bowel habits that lasts over 2 weeks

# Stop use and ask a doctor if

- you have rectal bleeding or fail to have a bowel movement after use of a laxative. These could be signs of a serious condition.
- you need to use a laxative for more than 1 week

### If pregnant or breast-feeding,

ask a health professional before use.

# Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

# **Directions**

• take only by mouth. Doses may be taken as a single daily dose or in divided doses.

adults and children 12 years and over	take 1-3 softgels daily
children 2 to under 12 years of age	take 1 softgel daily
children under 2 years	ask a doctor

#### Other information

- each softgel contains: sodium 6 mg
- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

# **Inactive ingredients**

D&C red #33,edible ink, FD&C blue#1\*, FD&C red#40, FD&C yellow#6, gelatin, glycerin, polyethylene glycol, propylene glycol\*, purified water, sorbitan, sorbitol, titanium dioxide

\*contains one or more of these ingredients

#### Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

# **Principal Display Panel**

†Compare to Colace® Regular Strength Stool Softener active ingredient

#### **Stool Softener**

Docusate Sodium 100 mg

stool softener laxative

#### **SOFTGELS**

†This product is not manufactured or distributed by Purdue Products L.P., distributor of Colace® Regular strength Stool Softener.

Distributed by AmerisourceBergen

1300 Morris drive, Chesterbrook, PA 19087

Questions or Concerns? Visit us at www.mygnp.com

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

#### **Product Labeling**



# GOOD NEIGHBOR PHARMACY Stool Softener

# STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46122-451
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	100 mg

Inactive Ingredients		
Ingredient Name	Strength	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		

GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	RED, WHITE	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	P10;SCU2;D1
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46122-451-72	1 in 1 BOX	10 /0 1/20 17	
1		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:46122-451-78	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10 /0 1/20 17	
3	NDC:46122-451- 85	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	10 /0 1/20 17	

# Labeler - AmerisourceBergen (Good Neighbor Pharmacy) 46122 (007914906)

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